



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,807	01/11/2002	Xuanchuan Yu	LEX-0298-USA	8020

7590 07/30/2003

Lance K. Ishimoto  
Lexicon Genetics Incorporated  
4000 Research Forest Drive  
The Woodlands, TX 77381

EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
----------	--------------

1652

DATE MAILED: 07/30/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/044,807

Applicant(s)

YU ET AL.

Examiner

Sheridan L. Swope

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 14 July 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation page.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-4.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Rejection of Claims 1-4 under 35 U.S.C. 101 because the claimed invention is not supported by a well established utility for either the nucleic acid molecule of SEQ ID NO: 1 or any nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2 is maintained. The claimed invention is not supported by an asserted utility based on either a demonstrated function for the protein of SEQ ID NO: 2 or by a deduced function for said protein supported by homology to known proteins.

The only new argument presented by the Applicants in the Request for Reconsideration is found on page 9, paragraph 1. Therein Applicants "point out that two sequences sharing nearly 100% identity at the protein level over an extended region of the claimed sequence is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by third party scientists ... as "Homo sapiens ADAMTS-like 1" variants 1 and 2 (GenBank accession number NM\_139238 and NM\_052866)". Applicants further state that "the scientists that described ADAMTS-like 1 have determined that the protein is localized to the extracellular matrix (Hirohata et al., J. Biol. Chem. 277: 12182-89, 2002)" and that "Given these two GenBank annotations and the manuscript by Hirohata et al, there can be no question that those skilled in the art would clearly believe that Applicants' sequence is an ADAMTS-like protease, and would thus readily understand the utility of the presently claimed sequence."

This new argument is not found to be persuasive for the following reasons. ADAMTS-like 1 variants 1 and 2 share 99% identity with SEQ ID NO: 2 over only 38% and 30%, respectively, of the full-length of SEQ ID NO: 2. Therefore, the function of the remaining 62% or 70% of the protein set forth by SEQ ID NO: 2 can not be deduced by homology to ADAMTS-like 1 variants 1 and 2. Since the major portion of the protein set forth by SEQ ID NO: 2 does not have homology with ADAMTS-like 1 variants 1 and 2, Applicant's contention that the function of the protein set forth by SEQ ID NO: 2 can be deduced from its homology to these two proteins is not supported. Furthermore, the function of ADAMTS-like 1 variants 1 and 2 is not clear. Hirohata et al teach that ADAMTS-like 1 contains only the nonenzymatic, ancillary domains and lacks the metalloprotease and disintegrin-like domains typical of ADAMTS proteases. Thus, any assertion that the protein set forth by SEQ ID NO: 2 of the instant application has protease activity can not be deduced by its homology to ADAMTS-like 1. The function of the ancillary domains of ADAMTS proteases is to localize these enzymes to substrates, the cell surface, or to the extracellular matrix. It is acknowledged that homology of the protein of the instant application with ADAMTS-like 1 may suggest that the protein set forth by SEQ ID NO: 2 is at the cell surface or in the extracellular matrix; however, such a suggestion does not support a deduced function for said protein. Hirohata et al do not claim or teach a specific, substantial, or credible function for their ADAMTS-like 1 protein. Therefore, clearly a specific, substantial, or credible function for the protein set forth by SEQ ID NO: 2 in the instant application can not be deduced by any homology to ADAMTS-like 1. For these reasons and those described in the prior action, rejection of Claims 1-4 under 35 U.S.C. 101 because the claimed invention is not supported by a well established utility for either the nucleic acid molecule of SEQ ID NO: 1 or any nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2 is maintained.

*Rebecca Hart*  
REBECCA HART  
PRIMARY EXAMINER  
GROUP 1200  
1000